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No. 74-759

In the Supreme Court of the United States

OCTOBER TERM, 1975

UNITED STATES OF AMERICA, PETITIONER

v.

THOMAS W. MOORE, JR.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

REPLY BRIEF FOR THE UNITED STATES

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1. Respondent argues (Brief, pp. 20–23) that decisions of this Court under the Harrison Narcotic Act should be disregarded because the Controlled Substances Act is "fundamentally different," in that under the new Act abuses by those in the "legitimate distribution chain" are to be policed "primarily by administrative rather than criminal sanctions." He relies in part upon the reports of the Prettyman Commission[1] and the Katzenbach Commission,[2] both of

[1] The President's Advisory Commission on Narcotic and Drug Abuse (1963).

[2] The President's Commission on Law Enforcement and Administration of Justice, *Task Force Report: Narcotics and Drug Abuse* (1967).

which were cited in the House Report on the Controlled Substances Act. See H.R. Rep. No. 91–1444, 91st Cong., 2d Sess. (Part 1) 16 (1970).

Both Commissions noted the reluctance of physicians under the Harrison Narcotic Act to dispense drugs in the legitimate treatment of narcotic addicts for fear of offending "the opinions of Federal prosecutors of what constitutes appropriate methods of professional practice." H.R. Rep. No. 91–1444, *supra,* at 15. However, both the Commissions and Congress presumed that a physician who treats addicts would act in good faith in accordance with elementary precautionary standards of medical practice. Nothing in the reports indicates that Congress or the Commissions intended to bar all criminal prosecutions of entire classes of persons such as registrants, practitioners, physicians or pharmacists, as respondent suggests.

The Katzenbach Commission expressly recognized that if a physician were to depart from accepted standards of medical practice and were to act "without the pretense of treatment, or a bona fide physician-patient relationship * * * he would clearly have violated the law." Katzenbach Commission, *supra,* at 19. Similarly, the Prettyman Commission, *supra,* at 56, and the House Report noted this Court's decisions under the Harrison Act that "the indiscriminate prescribing of narcotic drugs for addicts" was criminally punishable. H.R. Rep. No. 91–1444, *supra,* at 14. Thus, there is no basis in the reports of the Commissions or in the House Report for respondent's argument that Congress intended to exempt registrants or practi-

tioners as a class from prosecution under Section 841 of the Controlled Substances Act.[3]

The Prettyman and the Katzenbach Commissions both recommended action by Congress to reduce the "gray area" in the legitimate medical treatment of addicts which had made even those physicians who were honestly attempting to comply with accepted medical standards reluctant to treat addicts. Congress responded, not by enacting Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 84 Stat. 1242, 21 U.S.C. 801, *et seq.,* (the Controlled Substances Act) involved in this case, but by enacting Title I, specifically Section 4, 84 Stat. 1241, 42 U.S.C. 257a, which provides:

> The Secretary of Health, Education, and Welfare, after consultation with the Attorney General and with national organizations representative of persons with knowledge and experience in the treatment of narcotic addicts, shall determine the appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotic addicts, and shall report thereon from time to time to the Congress.

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[3] Indeed only the House Report makes reference to the Prettyman and Katzenbach Commissions. The Senate Judiciary Committee did not mention either Commission, and the sponsor of the Senate bill, Senator Dodd, while alluding to the need for separate legislation for treatment of addicts, stated:

"But it cannot be overemphasized that the bill before the Senate today is entirely concerned with enforcement.

"It contains no medical or rehabilitative provisions.

"It is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls." (116 Cong. Rec. 978 (1970).

The Commissions did not recommend, and Congress did not adopt, a change in the law so drastic as to exempt from prosecution those with the greatest access to controlled substances, physicians and pharmacists, when they distributed drugs indiscriminately and without medical justification. In the absence of such an expressed congressional intent, prior decisions of this Court under the Harrison Act demonstrate that drug trafficking physicians are not immune from prosecution under Section 841 of the Controlled Substances Act.[4]

2. Respondent also relies upon (Brief, p. 11) the recently enacted Narcotic Addict Treatment Act of 1974 (NATA), Pub. L. 93–281, 88 Stat. 124, as evidence that Congress intended to deal with registrants through a system of administrative controls rather than penal sanctions. But NATA was enacted after the events in question in this case. Moreover, there is no indication in NATA itself or in its legislative history that Congress had intended to exempt practitioners from criminal punishment under the Controlled Substances Act when they distribute for illicit purposes.

The purpose of NATA was to strengthen the ad-

[4] Indeed, respondent's conduct, as described in his own brief in this Court (pp. 4–5), is strikingly similar to the conduct held to have violated the Harrison Act in *Jin Fuey Moy* v. *United States*, 254 U.S. 189, 192–194.

[5] NATA imposed additional administrative controls on the registration of practitioners who dispense narcotic drugs to individuals for maintenance or detoxification treatment, by subjecting them to the same record-keeping and reporting requirements as non-physician registrants (21 U.S.C. 827(c)(1)(A), as amended, 88 Stat. 125), and by requiring of them a separate annual registration from the Attorney General, who must find that they will comply with standards established by him for these forms of treatment (21 U.S.C. 823(g), 88 Stat. 124). Previously, practitioners were entitled of right to registration if authorized to dispense under the law of the state in which they practiced. See 21 U.S.C. 823(f).

Similarly, NATA permits suspension or revocation of a registration to dispense for maintenance or detoxification "upon a finding that the registrant has failed to comply with any" of the aforementioned standards (21 U.S.C. 824, as amended, 88 Stat. 125). Previously, the Attorney General could revoke a registration only if the registrant had lost his state license, falsified an application or committed a drug-related felony. See 21 U.S.C. 824.

ministrative capability of the government to control a specific form of medical practice—treatment of drug addiction by detoxification or maintenance, principally using methadone. S. Rep. No. 93–192, 93d Cong., 1st Sess. 4 (1973).[5] The Act did not amend the Controlled Substances Act with regard to the distribution of methadone and other controlled substances for purposes not specifically designed for detoxification or maintenance, nor did it alter the criminal penalty provisions in any way. It therefore provides no more evidence than does the Controlled Substances Act itself of a congressional intent to deal with registrants solely through administrative controls rather than through the imposition of criminal sanctions in appropriate cases.

Moreover, by indicating that the impetus for the additional administrative remedies established by NATA was the difficulty of proving criminal conduct on the part of practitioners purporting to engage in unorthodox forms of detoxification or maintenance of addicts, Congress acknowledged that practitioners

may be prosecuted under Section 841. For example, the Senate Judiciary Committee recognized that the new "treatment modalities" of methadone maintenance and detoxification had increased the opportunity for the diversion of methadone into the illicit market (S. Rep. No. 93–192, *supra,* at 4), and that a principal source of that diversion was careless or unscrupulous physicians (*id.* at 6–7). It noted the difficulties inherent in proceeding criminally against such physicians masquerading behind the appearance of legitimacy afforded them by these new methods of treatment (*id.* at 12–14) and the inability "to take successful criminal action against profiteering practitioners except in the most aggravated of circumstances * * *" (*id.* at 13). The report specifically referred to respondent as the illustration of the exception, saying: "One of the most notorious cases is that of Dr. Thomas Moore who operated a 'methadone program' in the District of Columbia until his final conviction of illegal distribution of methadone on an indictment alleging 38 separate counts" (*id.* at 7).[6]

Against this background, NATA, like the Controlled Substances Act itself, is a further recognition by Congress that administrative and criminal

[6] Prosecution in such cases had been time-consuming, requiring "prolonged effort to make undercover penetrations" (S. Rep. No. 93–192, *supra*, at 13); and during this prosecutorial effort, registrations could not be suspended or revoked because of the limited grounds the Controlled Substances Act provided for suspension and revocation. Respondent was specifically named as a "dangerous profiteer" against whom the Attorney General "could have moved * * * far more expeditiously" if he had possessed broader

sanctions must be used in a complementary fashion to stem the illicit diversion of controlled substances by unscrupulous practitioners. NATA merely reemphasized Congress' belief that the war against drug diversion had to be waged on both fronts. See S. Rep. No. 93–192, *supra,* at 13–14.

3. Respondent makes several contentions with respect to 21 C.F.R. 306.04 (1973).[7] That regulation is contained in Part 306 (now Part 1306) of Title 21 of the Code of Federal Regulations, which "govern[s] the issuance, filling and filing of prescriptions pursu-

power to revoke registrations (*id.* at 7). Moreover, when a maintenance program that was a source of illicit street drugs had been terminated by the threat of prosecution, the physician then often emerged as the operator of a detoxification program which, under prior law, was not subject to the same kind of federal regulations as were maintenance programs (*id.* at 12). Again, respondent was named as the "most notorious example of this type of maneuver" (*ibid.*). Finally, prosecution had been deterred by "the intricate and nearly impossible burden of establishing what is beyond 'the course of professional practice' for criminal law purposes when * * * a practitioner speciously claims that the practices in question were ethical and humanitarian in nature" (*id.* at 14).

[7] 21 C.F.R. 306.04 (1973) provided in pertinent part:

"(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided

ant to section 309 of the Act (21 U.S.C. 829) * * *." 21 C.F.R. 306.01. Section 306.04, along with the other regulations contained in Part 306, was promulgated by the Attorney General pursuant to his statutory authority "to promulgate rules and regulations * * * relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances." 21 U.S.C. 821. See also 21 U.S.C. 829, 871(b). It is an administrative regulation designed to effectuate the registration and other regulatory provisions of the Controlled Substances Act.

a. Respondent first claims (Brief, pp. 12–15) that by relying upon the regulation as "in the nature of a Bill

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for violations of the provisions of law relating to controlled substances.

* * * * *

"(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his dependence upon such drugs, in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program."

The regulation was redesignated 21 C.F.R. 1306.04 in the 1974 revision of Title 21 of the Code of Federal Regulations and remains so designated in the 1975 revision. For convenience and so that it is clear that we are referring to the regulation as it existed at the time of respondent's trial, we will refer to the regulation throughout this brief as 21 C.F.R. 306.04. Similarly references to other pertinent regulations in Title 21 will be to the regulations as they were designated in the 1973 edition of the Federal Code of Regulations. We note, however, that subsection (c), as amended on October 25, 1974, now reads:

"(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule for 'detoxification treatment' or 'maintenance treatment' as defined in Section 102 of the Act" (21 U.S.C. 802).

of Particulars" (App. 37), the government took the position at trial that respondent, although an "authorized" person under 21 U.S.C. 841, violated the regulation and thereby violated Section 841 of the Act. From this premise, he argues that his conviction cannot stand because Congress attached no criminal penalties to the regulation upon which the government relied. Our answer is that the indictment, the evidence, the jury instructions and the verdict in this case all focused on conduct constituting the violation of a specific statute, 21 U.S.C. 841(a), not a regulation.

The Controlled Substances Act itself, not the regulation, creates certain exceptions for "authorized" conduct.[8] Among the conduct the Act authorizes is the dispensing of a controlled substance by a practitioner pursuant to a lawful order and "in the course of professional practice." See 21 U.S.C. 802(10), 802(20). 21 C.F.R. 306.04 simply restates this statutory limitation. It does not, as respondent intimates, attempt to make punishable conduct that the statute

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[8] Contrary to respondent's assertion, the government's theory at trial was not that, although he may have been an "authorized" *person* within the meaning of Section 841, respondent violated 21 C.F.R. 306.04 and thereby violated Section 841. The government did not concede at trial that respondent was an "authorized" person under Section 841. Its theory then, as now, was that Section 841 does not exempt from criminal prosecution a class of persons (registrants) but rather exempts certain "authorized" *conduct* by, *inter alia*, practitioners who dispense drugs "in the course of professional practice." Sec. 21 U.S.C. 802(10), 802(20). When a practitioner distributes other than in the course of professional practice, he exceeds his authorization, is no longer a practitioner authorized to dispense under the Act and is thus punishable under Section 841 like anyone else.

itself does not proscribe or itself impose criminal liability on distributing for unauthorized purposes.

Rather, by authorizing the prescription of controlled substances only "for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice" (21 C.F.R. 306.04), the regulation does not "go outside of the circle of that which the [Controlled Substances] Act itself [has] affirmatively required to be done, or treated as unlawful if done." *United States* v. *Grimaud*, 220 U.S. 506, 518. Thus, it is the statute and not the regulation that makes respondent's conduct punishable.

Because 21 C.F.R. 306.04 restated and explicated the statutory standard "in the course of professional practice," it served as a useful partial "bill of particulars" in describing the government's theory to the trial court and to respondent and his counsel.[9] How-

[9] In brief, the government's theory was that respondent had issued methadone prescriptions other than for purposes of detoxification, that such issuance was not in the course of legitimate professional practice and that respondent thereby violated 21 U.S.C. 841(a)(1). 21 C.F.R. 306.04(a) restates the doctor's authority to dispense through prescriptions, which must "be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." The government contended that "the conduct by Dr. Moore in giving out these prescriptions was not for a legitimate medical purpose, and * * * that he was not acting in the usual course of his professional practice" (App. 36). The prosecutor also made reference to language in 21 C.F.R. 306.04(c) and advised the court that the government intended to prove that respondent "was not issuing * * * prescriptions to detoxify [addicts], but retaining them as drug addicts" (App. 36–37).

The prosecutor's statement of his theory was made at a pretrial hearing more than one month before jury selection and commencement of the trial. The jury was never made aware of

ever, the issue before the jury was whether respondent had violated the Controlled Substances Act, not merely a regulation, by conduct which was contrary to any bona fide professional medical practice. As the court of appeals acknowledged (Pet. App. 3a–4a), the government's proof was intended to show that respondent had prescribed methadone in a manner contrary to any legitimate method of treating addiction, whether by detoxification or maintenance; and the prosecution's evidence did not demonstrate solely that respondent violated the regulation or the terms of his registration, "but much more broadly [that] his alleged activities [were] outside the 'usual course of [professional] practice' " (Pet. App. 8a, n. 18).[10]

Thus the question for the jury was whether respondent had distributed controlled substances other than in good faith for treatment and outside the usual course of professional practice. As we explained in

the theory as embodied in the prosecutor's statement to the court. Moreover, the prosecutor had no advance notice that he was going to be required to make a statement of his theory at the hearing. Indeed, although respondent's counsel had previously announced his intention to file a motion for a bill of particulars, he in fact never made such a motion (see July 13, 1972 Tr. 8–9), and therefore a bill of particulars was never filed. Compare Rule 7(f), Fed. R. Crim. P.

[10] The government's evidence was designed to show not that respondent had prescribed methadone pursuant to an otherwise bona fide maintenance program, but that he had prescribed contrary to *any* legitimate treatment method, whether detoxification or maintenance. See, *e.g.*, App. 80–83, 88, and our brief, pp. 10–13. Expert testimony at trial demonstrated that respondent's conduct did not constitute "acceptable medical practice" for either the detoxification or maintenance of addicts. App. 78–90.

our main brief (pp. 20–26, 33–38) this is the statutory standard for practitioners under 21 U.S.C. 841(a).[11]

There is no meaningful distinction, as respondent claims (Brief, p. 17), between the statutory standard "in the course of professional practice" and the phrase "in the usual course of his professional practice" in the regulation. Neither Congress nor the Attorney General intended the standard of authorized dispensing to depend on the subjective views of a practitioner as to what constitutes legitimate medical practice. Moreover, the fact that the word "his" was used to modify "professional practice" in the Harrison Narcotic Act did not prevent this Court in the past from concluding that the standard of authorized dispensing turned on an objective assessment of the facts and circumstances and not on the opinion of a particular physician. For the "[m]ere pretense of [professional] practice * * * cannot legalize forbidden sales." *Linder* v. *United States,* 268 U.S. 5, 18. See also *United States* v. *Behrman,* 258 U.S. 280, 287; *Jin Fuey Moy* v. *United States,* 254 U.S. 189, 194; *Webb* v. *United*

[11] Respondent's claim (Brief, pp. 17–19), that the government failed to prove that he had violated the regulation, is therefore irrelevant. For, as we have shown, he was charged with and convicted of having violated a statute, not a regulation. Respondent has neither alleged nor demonstrated that the government's reference to the regulation, in outlining its theory of the case, out of the presence of the jury and well before trial, prejudiced him in the preparation or presentation of his defense. Indeed, since the standard in the regulation is precisely that contained in the statute, respondent had adequate notice of the conduct proscribed by the statute and the proof against which he would have to defend.

States, 249 U.S. 96, 99–100. Finally, the trial judge gave sufficient consideration to differing theories of what constitutes legitimate dispensing by instructing the jury that respondent was required to make only an "honest effort" to comply with accepted medical standards (App. 124).[12]

b. Respondent also contends (Brief, p. 16) that because 21 C.F.R. 306.04 was promulgated in order to implement 21 U.S.C. 829, and because violations of Section 829 are specified in Section 842, not Section 841 of the Controlled Substances Act, he was liable for a maximum one-year sentence under Section 842 for violating the regulations. However, 21 U.S.C. 829 merely establishes formal requirements for the issuance of prescriptions by pharmacists.[13] It does not impose—but rather presupposes— the requirement that a prescription must be issued by a phy-

[12] The trial judge instructed the jury that to convict respondent it must find that he dispensed or distributed "other than in good faith for detoxification" (App. 123). Respondent did not object to this instruction. See Tr. V 67–69, 71–79 and our brief at p. 6, n. 10. Moreover, as the court of appeals found (Pet. App. 3a), respondent's defense at trial was not that he had prescribed for maintenance rather than detoxification, but "that he prescribed methadone in good faith for detoxification." See also Tr. IV 649. He could not be prejudiced by an instruction by the court tailored to this defense, and, as we noted, one to which he did not object.

[13] Subsection (a) provides that "[e]xcept when dispensed directly by a practitioner other than a pharmacist, to an ultimate user, no controlled substance in schedule II * * * may be dispensed without the *written* prescription of a practitioner * * *" (emphasis added). Subsection (b), in turn, declares that a schedule III or IV controlled substance may not be dispensed (except directly by a physician) without either "a written or oral prescription."

sician in the course of his professional practice for a legitimate medical purpose. That requirement, as we explained in our main brief, is imposed by Sections 841 and 822(b) by reference to the "other provisions" of the Act, including the statutory definition of a "practitioner." Section 842(a)(1), on the other hand, penalizes "more or less technical violations" (H.R. Rep. No. 91–1444, *supra*, pp. 10–11) of the formal requirements of when a written rather than an oral prescription is required by Section 829.[14]

Similarly, Part 306 of Title 21, Code of Federal Regulations, is concerned with the differing formal requirements in the issuance of written and oral prescriptions by pharmacists. See 21 C.F.R. 306.11 through 306.32. Violation of such requirements subjects one to the penalties of 21 U.S.C. 842. At the same time, however, 21 C.F.R. 306.04(a), which the government used as "in the nature of a Bill of Particulars," contains the directive that "[a]n order * * * issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of [21 U.S.C. 829] and the person * * * issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." The regulation thereby gives notice to practitioners that a prescription issued other

[14] Any other interpretation of Section 829 in its relation to the penal sections of the Act would lead to the absurd result (noted in our main brief, at page 30) that a practitioner who sold or gave schedule II–IV drugs directly to persons for an illicit purpose rather than wrote prescriptions for the drugs would not be punishable at all under the Act, since Section 829 deals only with prescriptions.

than for a legitimate medical purpose—even if in compliance with the formal requirements of Section 829—is conduct unauthorized by the Controlled Substances Act, is not within its protection and subjects the issuer to punishment for unauthorized distribution under 21 U.S.C. 841. Thus, contrary to respondent's assertion, 21 C.F.R. 306.04 does not limit the punishment of registrants who wrongfully prescribe controlled substances to the misdemeanor penalties of 21 U.S.C. 842.[15]

4. Finally, respondent argues (Brief, p. 6, n. 8) that even should this Court disagree with the conclusion of the court of appeals concerning respondent's immunity from prosecution under 21 U.S.C. 841(a), the case must be remanded to that court to consider whether respondent was properly sentenced under 21 U.S.C. 845, a statute which provides that where a person over 18 sells to a person under 21, punishment for a first offense may be twice that otherwise prescribed. Since the court of appeals did not reach that question and (unlike respond-

[15] As we pointed out in our main brief at page 44, the District of Columbia Circuit is alone in having concluded that physicians and other practitioners are immune from prosecution under Section 841 of the Controlled Substances Act. Since the filing of our brief, the Sixth Circuit has implicitly joined the First, Fifth, Seventh, Ninth and Tenth Circuits in concluding that physicians and other practitioners are not immune from prosecution under 21 U.S.C. 841. See *United States* v. *Carroll*, 518 F. 2d 187 (C.A. 6). Moreover, following its opinion in *United States* v. *Rosenberg*, 515 F. 2d 190, the Ninth Circuit has held that pharmacists, like physicians and other practitioners, are not immune from prosecution under 21 U.S.C. 841(a)(1). See *United States* v. *Norman*, C.A. 9, No. 74–2465, decided August 6, 1975.

ent's arguments with respect to the regulation) it is not integrally related to the issue upon which this Court granted certiorari, we agree that a remand will be necessary.

Accordingly, the judgment of the court of appeals should be reversed and the case remanded to that court for the sole purpose of considering whether respondent was properly sentenced under 21 U.S.C. 845 for distributing a controlled substance to persons under 21 years of age.

Respectfully submitted.

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